





PATENT

#10  
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3/7/01

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: J. Phillips

Serial No.: 09/481,207

Filed: January 11, 2000

For: NOVEL SUBSTITUTED  
BENZIMIDAZOLE DOSAGES FORMS  
AND METHOD OF USING SAME

Attorney Docket No.: 40015630-0004


Date: February 28, 2001

Examiner: J. Fan

Group Art Unit: 1625

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Jo Ellen Hogan Date

## INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

The following information is submitted, pursuant to 37 CFR §§1.97-1.98 in accordance with Applicant's duty of disclosure under 37 CFR §1.56. This submission is not intended to constitute an admission that any patent, publication or other information cited herein is "prior art" as to the invention claimed. In accordance with 37 CFR §§1.97(g)-(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that other material information as defined by 37 CFR §1.56(a) exists.

Applicants submit herewith Form PTO 1449 listing the references cited in this Information Disclosure Statement. Applicants respectfully request that the Examiner (1) initial each reference listed on the enclosed Form PTO 1449 indicating that the Examiner has considered and made those references of record in this application and (2) return a copy of the initialed Form PTO 1449 to Applicants. Copies of the references are also enclosed. Designated references "\*" were submitted in parent application serial no. 08/680,376, now U.S. Patent No. 5,840,737 and are not included herewith. Applicants are in the process of gathering copies of the highlighted references and these references will follow.


This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits under 37 CFR §1.97(b), and Applicants believe no fee is due. However, should additional filing fees under 37 CFR 1.17(p) be required, the Commissioner is hereby authorized to charge Deposit Account 19-3140.

Respectfully submitted,

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## Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE  
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ATTY. DOCKET NO.

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INFORMATION DISCLOSURE  
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(37 CFR 1.98 (b))

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
		4 0 4 5 5 6 4	08/30/77	Berntsson, et al.			
		4 1 8 2 7 6 6	09/11/78	Krasso, et al.			
		4 2 5 5 4 3 1	04/05/79	Junggren, et al.			
		4 3 3 7 2 5 7	06/29/82	Junggren, et al.			
		4 4 7 2 4 0 9	10/29/82	Senn-Bilfinger			
		4 5 4 4 7 5 0	10/01/85	Brandstrom			
		4 6 2 0 0 0 8	10/28/86	Brandstrom			
		4 6 3 6 4 9 9	01/13/87	Brandstrom			
		4 7 2 5 6 9 1	02/16/88	Brandstrom			
		4 7 3 8 9 7 4	04/19/88	Brandstrom			
		4 7 8 6 5 0 5	11/22/88	Lovgren, et al.			
		4 8 5 3 2 3 0	08/01/89	Lovgren, et al.			
		5 0 0 8 2 7 8	04/16/91	Brandstrom			
		5 0 1 3 7 4 3	05/07/91	Iwahi, et al.			
		5 0 1 9 5 8 4	05/28/91	Brandstrom			
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		5 0 3 9 8 0 6	08/13/91	Brandstrom, et al.			
		5 0 4 5 3 2 1	09/03/91	Makino, et al.			
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		5 6 9 0 9 6 0	11/25/97	Bengtsson			
		5 6 9 3 8 1 8	12/02/97	Von Unge			
		5 7 1 4 5 0 4	02/03/98	Lindberg, et al.			

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	5	7	1	4	5	0	5	02/03/98	Hasselkus			
	5	7	3	1	0	0	2	03/24/98	Olovson			
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	5	7	6	6	6	2	2	09/05/95	Nelson			
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	5	8	4	0	7	3	7	11/24/98	Phillips			
	5	8	7	7	1	9	2	03/02/99	Lindberg, et al.			
	5	8	8	3	1	0	2	03/16/99	Hamley, et al.			
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	5	9	6	5	1	6	2	10/12/99	Fuisz, et al.			
	5	9	7	9	5	1	5	11/09/99	Olsson			
	6	0	1	3	2	8	1	01/11/00	Lundberg			

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER							PUBLIC- ATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS- LATION	
		YES	NO											
		8	8	3	5	1			30.04.86	RO				
		2	1	8	9	6	9	8	04.11.87	UK				
		1	2	3	4	1	1	8	03.15.88	CA				
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		9	4	0	0	1	1	2	06.01.94	WO				
		9	4	0	2	1	4	0	03.02.94	WO				
		9	5	3	2	9	5	7	07.12.95	WO				
		9	6	0	1	6	1	2	25.01.96	WO				
		9	6	9	1	6	2	2	25.01.96	WO				
		9	6	2	4	3	7	5	15.08.96	WO				
		9	7	2	5	0	3	0	17.07.97	WO				
		9	7	4	1	1	1	4	06.11.97	WO				
		9	7	4	8	3	8	0	24.12.97	WO				
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		9	8	5	0	0	1	9	12.11.98	WO				

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		9	9	3	2	0	9	3	01.07.99	WO				
		0	0	2	6	1	8	5	11.05.00	WO				

## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		"Agents for Control of Gastric Acidity and Treatment of Peptic Ulcers", Chapter 37, pp. 907-909.
		"An Updated Review of its Pharmacology and Therapeutic Use in Acid-Related Disorders" by D. McTavish, et. al., <u>Drugs</u> , Vol. 41, No. 1, pp. 138-170 (1991).
		"Omeprazole, Overview and Opinion" by S. Holt and C.W. Howden, <u>Digestive Diseases and Sciences</u> , Vol. 36, No. 4, pp. 385-393 (April 1991).
		"Pantoprazole, A Review of its Pharmacological Properties and Therapeutic Use in Acid-Related Disorders" by A. Fitton and L. Wiseman, <u>Drugs</u> , Vol. 51, No. 3, pp. 460-482 (March 1996).
		"Differential Stereoselective Pharmacokinetics of Pantoprazole, a Proton Pump Inhibitor in Extensive and Poor Metabolizers of Pantoprazole - A Preliminary Study" by M. Tanaka, et. al. <u>Chirality</u> , Vol. 9, pp. 17-21 (1997).
		"A prospective study of simplified omeprazole suspension for the prophylaxis of stress-related mucosal damage" by Phillips, et. al., <u>Crit Care Med</u> , Vol. 24, No. 11, pp. 1793-1800 (1996).
		"A prospective study of omeprazole suspension to prevent clinically significant gastrointestinal bleeding from stress ulcers in mechanically ventilated trauma patients" by M. Lasky, <u>The Journal of Trauma: Injury Infection, and Critical Care</u> , Vol. 44, No. 3, pp. 527-533 (1998).
		"Effect of combined administration of lansoprazole and sofalcone on microvascular and connective tissue regeneration after ethanol-induced mucosal damage" by Nakamura M, et. al., <u>J. Clin. Gastroenterol.</u> , Vol. 27, Supp. 1, pp. 170-77 (1998).
		"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement [Date stamped in Howard University Library on January 13, 1995].

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## Form PTO - 1449 (Modified)


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## OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

/	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement [Date stamped in Walter Reed Army Medical Center Medical Library on January 17, 1995].
/	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in FDA Medical Library January 6, 1995].
/	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in University of Illinois on January 10, 1995].
/	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in Central DuPage Hospital Medical Library on January 10, 1995].
/	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan 1995) [Date stamped in University of Missouri Health Sciences Library January 6, 1995].
/	"The Effect of Omeprazole/Sodium Bicarbonate Solution Administration on the Accuracy of Subsequent pH Measurements Through the Nasogastric Tube" by J. Phillips, <u>Crit Care Med</u> , Vol. 23, No. 1 Supplement (Jan. 1995). [Although allegedly date stamped in St. Vincent's Hospital Medical Library on January 3, 1995, interviews of library personnel revealed that this Supplement was not received until Jan. 9, 1995, as the January 9, 1995 date is found in their computerized database.]
	"Lansoprazole capsules and amoxicillin oral suspension in the treatment of peptic ulcer disease" by Hatlebakk JG, et. al., <u>Scand. J. Gastroenterol.</u> , Vol. 30, No. 11, pp. 1053-57 (1995).
	"Nicotinamide pharmacokinetics in humans: effect of gastric acid inhibition, comparison of rectal vs oral administration and the use of saliva for drug monitoring" by M.R. Stratford, et. al. <u>J Cancer</u> , Vol. 74, No. 1, pp. 16-21 (July 1996).
	"Comments of the report of 'association' of omeprazole with DNA by Phillips, et. al." by S.P. Adams <u>Mutagenesis</u> , Vol. 7, No. 5, pp. 395-396 (September 1992).
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	"Simplified omeprazole solution for the prophylaxis of stress - related mucosal damage", <u>Crit. Care Med</u> , 22: A53 (1994).
	"Effective gastric acid suppression after oral administration of enteric-coated omeprazole granules" by M.A. Mohiuddin, et. al. <u>Dig Dis Sci</u> , Vol. 42, No. 4, pp. 715-719 (April 1997).
	"Endoscopic topical therapy for the treatment of Helicobacter pylori infection" by K. Kihira, et. al. <u>J Gastroenterol</u> , Vol. 31, Suppl 9, pp. 66-68 (November 1996).

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		"Pharmacokinetic evaluation of omeprazole suspension following oral administration in rats: effect of neutralization of gastric acid" by K. watanabe, et. al. <u>Acta Med Okayama</u> , Vol. 50, No. 4, pp. 219-222 (August 1996).
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		"Synthesis and structure-activity relationships of substituted 2-[2-imidazolylsulfinyl)methyl] anilines as a new class of gastric H+/K(+)-ATPase inhibitors. II." by T. Yamakawa <u>Chem Pharm Bull</u> (Tokyo), Vol. 40, No. 3, pp. 675-682 (March 1992)
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		"Nasogastric Administration of Omeprazole" <u>The Australian Journal of Hospital Pharmacy</u> , Vol. 28, No. 3 (1998).
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		"Nasogastric Omeprazole: Effects on Gastric pH in Critically Ill Patients" by D. Balaban, et. al., <u>Am J of Gastroenterology</u> , Vol. 92, No. 1, pp. 79-83 (1997).
		"Comparison of 24-hour intragastric pH using four liquid formulations of lansoprazole and omeprazole" by V. Sharma, <u>Am J Health-Syst Pharm</u> , Vol. 56, Suppl 4, pp. S18-S21, (December 1, 1999).
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	*	"Pharmacokinetics of [ <sup>14</sup> C]Omeprazole in Patients with Liver Cirrhosis" by T. Andersson, <u>Clin Pharmacokinet</u> , Vol. No. 1, pp. 71-78 (1993)
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	*	"Let's agree on terminology: definition of sepsis" by Bone, <u>Crit. Care Med.</u> , Vol. 19, p. 27 (1991).
	*	"Antacids vs. sucralfate in preventing acute gastrointestinal tract bleeding in abdominal aortic surgery" by Borrero, et al., <u>Arch. Surg.</u> , Vol. 121, pp. 810-12 (1986).
	*	<u>The Pharmacologic Basis of Therapeutics</u> by Brunton, p. 907 (1990).
	*	"Central nervous system reactions to histamine-2 receptor blockers" by Cantu & Korek, Vol. 114, pp. 1027-34 (1994).
	*	"Comparison of acid neutralizing and non-acid neutralizing stress ulcer prophylaxis in thermally injured patients" by Cioffi, et al., Vol. 36, pp. 541-47 (1994).
	*	"Risk factors for gastrointestinal bleeding in critically ill patients" by Cook, et al., Vol. 330, pp. 377-81 (1994).
	*	"Stress ulcer prophylaxis in the critically ill: a meta analysis" by Cook et al., Vol. 91, pp. 519-27 (1991).
	*	"Nasocomial pneumonia and the role of gastric pH: a meta analysis" by Cook, et al., Vol. 100, p. 7-13 (1991).
	*	"Acute gastroduodenal disease after thermal injury: an endoscopic evaluation of incidence and natural history" by Czaja, et al., Vol. 291, pp. 925-29 (1974).
	*	"Does pH paper accurately reflect gastric pH?" by Dobkin et al., Vol. 18, pp. 985-88 (1990)

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